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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/394,264	09/10/99	MORTON C	10286/008001

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EXAMINER	
WINKLER,U	
ART UNIT	**PAPER NUMBER**
1648	8

DATE MAILED: 09/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/394,264	MORTON ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *26 June 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 18* is/are pending in the application.

4a) Of the above claim(s) *8-17 and 19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group I in Paper No. 6, filed 26 June 2000 is acknowledged.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 7, is attached to the instant Office action.

Drawings

The drawings are objected to, please see notice of Draftspersons' Review. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1 it is not clear what is meant by "naturally occurring allelic variant"; is the claim referring to variants due to the degeneracy of the genetic code and thereby claiming nucleic acids that code for the protein of SEQ ID:2; or does this also include changes in the protein sequence?

In claim 4 it is not clear what is meant by "heterologous polypeptide"; will this just include sequences that are used for protein purification purposes, or does this include a fusion with any undisclosed protein that may or may not have therapeutic properties?

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are drawn a naturally occurring allelic variant of SEQ ID:2. The

specification discloses an isolated cDNA sequence, SEQ ID NO: 1, which encodes a predictive polypeptide sequence, SEQ ID NO. 2. The broadly claimed allelic variants could include proteins that are functionally similar. The instant disclosure of a single species of nucleic acid coding for a single polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed polypeptide. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. The structure of these elements is not conventional in the art and a skilled artisan would therefore not recognize from the disclosure that applicant was in possession of the genus of nucleic acids, representing SEQ ID NO:1. Therefore, there is lack of written description in the instant specification for the claimed allelic variants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Robetson et al. (Genomics, December 1997).

The instant invention is drawn to nucleic acids of SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. In addition, the invention includes variants and sequences that have 60% identity with the disclosed nucleic acids.

Roberston et al. disclose GenBank/EMBL submission of sequences AF006741 and AF006740 which are identical matches to SEQ ID NO: 1 and 3 of the instant invention. Therefore, the instant invention is anticipated by Robertson et al.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) or 102(b), depending on the date of public availability, as being anticipated by sequence AF006741 (GenBank/EMBL, direct submission, 4 June 1997) and sequence AF006740 (GenBank/EMBL, direct submission, 4 June 1997) .

The instant invention is drawn to nucleic acids of SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. In addition, the invention includes variants and sequences that have 60% identity with the disclosed nucleic acids.

The GenBank/EMBL submission discloses sequences AF006741 and AF006740 which are identical matches to SEQ ID NO: 1 and 3 of the instant invention. Therefore, the instant invention is anticipated by sequence AF006741 and AF006740.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Heller et al. (PNAS, September 1998).

The instant invention is drawn to nucleic acids of SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. In addition, the invention includes a fragment that comprises at least 15 contiguous amino acid residues of SEQ ID NO: 2.

Heller et al. disclose GenBank/EMBL submission AF012252 which contains stretches of nucleic acids that code for greater than 15 contiguous amino acids of SEQ ID NO:2. Therefore, the instant invention is anticipated by Heller et al.

Claim 1 is rejected under 35 U.S.C. 102(a) or 102(b), depending on the date of public availability, as being anticipated by sequence AF012252 (GenBank/EMBL, direct submission, 2 July 1997).

The instant invention is drawn to nucleic acids of SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. In addition, the invention includes a fragment that comprises at least 15 contiguous amino acid residues of SEQ ID NO: 2.

The GenBank/EMBL submission discloses sequence AF012252 which contains stretches of nucleic acids that code for greater than 15 contiguous amino acids of SEQ ID NO:2. Therefore, the instant invention is anticipated by sequence AF012252.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Robertson et al. (Genomics 1994).

The instant invention is drawn to nucleic acids of SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. In addition, the invention includes a fragment that comprises at least 15 contiguous amino acid residues of SEQ ID NO: 2.

Robertson et al. disclose GenBank/EMBL submission of sequence U09203 which contains stretches of nucleic acids that are sufficient to code for greater than 15 contiguous amino acids of SEQ ID NO:2. Therefore, the instant invention is anticipated by Robertson et al.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by VanCoillie et al. (Genomics, March 1997).

The instant invention is drawn to nucleic acids of SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. In addition, the invention includes nucleic acids that have 60% sequence identity with SEQ ID NO: 1 or 3.

VanCoillie et al. disclose GenBank/EMBL submission of sequence Z78142 which shares greater than 60% sequence identity with SEQ ID:3. Therefore, the instant invention is anticipated by VanCoillie et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Robertson et al. (Genomics 1994).

The instant invention is drawn to nucleic acids represented by SEQ ID NO: 1 and 3, and nucleic acids encoding the polypeptide of SEQ ID NO:2. The invention includes a fragment that comprises at least 15 contiguous amino acid residues of SEQ ID NO: 2. In addition the invention includes a kit comprising a compound that selectively hybridizes the nucleic acids molecule of SEQ ID No:1.

Robertson et al. teach GenBank/EMBL submission AF012252 which contains stretches nucleic acids that are sufficient to code for greater than 15 contiguous amino acids of SEQ ID NO:2. The sequence was used as a probe to detect the distribution of Coch-5b2 (see figure 2). The reference does not teach formulating the probe into a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the probe into a kit for diagnostic purposes. One having ordinary skill in the art would have been motivated to do package the required components into a kit for the sake of conveniently providing the reagents to unskilled personnel. Therefore, the instant invention is obvious over Robertson et al.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robetson et al. (Genomics, December 1997) in view of the Pharmacia Catalog (1996).

The instant invention is drawn to nucleic acids an expression vector containing nucleic acids in a host cell.

Robertson et al. teaches the nucleic acid sequences of SEQ ID NO: 1 and 3. The reference does not teach inserting the sequences into an expression vector.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to take the nucleic acid sequences as taught by Roberston et al. and insert them into expression vectors in order to produce the encoded polypeptides. Inserting nucleic acid into expression vectors is routine to one of ordinary skill in the art as evidenced by the numerous of prokaryotic and eukaryotic expression vectors and competent host cells that are commercially available (see Pharmacia Catalog). One having ordinary skill in the art would have been motivated to do this in order to obtain a sufficient quantity of polypeptide which can then be used for functional studies as well as for the production of antibodies that can be used for diagnostic purposes. Therefore, the instant invention is obvious over Robertson et al. in view of the Pharmacia Catalog.

Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over VanCoillie et al. (Genomics, March 1997), Robertson et al. (Genomics 1994) or Heller et al. (PNAS, September 1998) each in view of the Pharmacia Catalog (1996).

The instant invention is drawn to nucleic acids an expression vector containing nucleic acids in a host cell.

The relevance of the sequences taught by VanCoillie et al., Robertson et al. or Heller et al. has been discussed above. It would have been obvious to one of ordinary skill in the art at the

time the invention was made to take the nucleic acid sequences as taught by VanCoillie et al., Robertson et al. or Heller et al. and insert them into expression vectors in order to produce the encoded polypeptides. Inserting nucleic acid into expression vectors is routine to one of ordinary skill in the art as evidenced by the numerous of prokaryotic and eukaryotic expression vectors and competent host cells that are commercially available (see Pharmacia Catalog). One having ordinary skill in the art would have been motivated to do this in order to obtain sufficient quantity of polypeptide which can then be used for functional studies as well as for the production of antibodies that can be used for diagnostic purposes. Therefore, the instant invention is obvious over VanCoillie et al., Robertson et al. or Heller et al. each in view of the Pharmacia Catalog.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER